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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

A CORNELIA

ART UNIT

PAPER NUMBER

DATE MAILED: 06/03/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/477,316

Applicant(s)

Gray et al.

Examiner

Ardin Marschel

Group Art Unit

1809

☒ Responsive to communication(s) filed on

3/10/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 is/are pending in the application.

~~or the above~~ Claim(s) 2-47 ~~is/are withdrawn from consideration.~~ *have been cancelled*

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, ~~Paper Note~~ *Label*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1809.

If the applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

Applicants' arguments, filed 3/10/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim 1 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 6-7, the phrase "high complexity nucleic acid probe" is vague and indefinite as to what is meant thereby for the metes and bounds of the probe practice. In the specification on page 42-43, bridging paragraph, a probe (singular) or "probes" (plural) are described as being interchangeable terms. This suggests that the intended instant "probe" practice includes singular or plural nucleic acid

polynucleotides. In claim 1, line 7, the probe is cited as a "probe of greater than 50,000 bases" which is reasonably interpretable as limiting the probe to one, singular, nucleotide segment and not to plural polynucleotides. Additionally, lines 2-3 of claim 1 cites "high complexity nucleic acid probes" (plural). This seems to conflict with the above singular citations. Clarification is requested as to clearer claim wording regarding the metes and bounds of probe practice in claim 1. This rejection is necessitated by amendment.

Claim 1 is vague and indefinite in that the metes and bounds of the hybridization conditions are not defined to correspond to the "staining targeted chromosomal material" in line 1. It is well known in the art that hybridization can be accomplished with a wide range of conditions such as low, medium, or high stringency. A complex target such as the nucleic acids from humans may produce a variety of hybridization results given the conditions of hybridization and the probe usage. In this application a high complexity probe is claimed without defined hybridization conditions. Such a high complexity probe would be expected to hybridize to some human nucleic acid under most hybridization conditions, including low, medium, and high stringency. As worded claim 1 lacks any limitation on the hybridization conditions connected with the desire to stain a "target" in the first line therein. Does this suggest that "any" hybridization condition will result in the proper target of interest staining? This is unlikely and would be unexpected.

Clarification is requested as to what practice actually produces the desired target nucleic acid staining cited in the first line of claim 1. This rejection is necessitated by amendment.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 1 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Weissman et al.

This rejection is maintained and reiterated as given in the previous office action, mailed 9/4/96. As discussed previously the reference is directed to the selection and usage of unique

sequence probes in hybridization assays. Such assays detect chromosomal segments by being labeled and hybridization which is the same practice as the instantly given staining. Also, probe regions of 50,000 bases to 2,000,000 bases are disclosed in column 9, lines 14-32, which clearly encompasses the instant probe complexity. In summary, it is not seen how applicants' arguments that the reference does not support the rejection is persuasive, therefore resulting in the continued presence of this rejection. It is noted that applicants' allegation that the reference does not support the rejection is in conflict with the factual evidence that it does as summarized herein and in the previous office action.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending application Serial No.

08/487,701; and claim 1 of 08/478,387; although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending applications contain common embodiments directed to high complexity probe methodology. This rejection is necessitated by amendment.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The disclosure is objected to because of the following informalities:

It is noted that part of the Request for Filing the instant application, filed 6/7/95, included the insertion of priority/parentage applications before the first line of the specification. This insertion is confusing in that applicants did not delete the priority/parentage citation paragraph in the section entitled "RELATED APPLICATION" on the first page of the specification. The confusion is that the specification now contains two paragraphs regarding related applications wherein these two paragraphs are different and inconsistent.

Appropriate correction is required.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL

ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group

1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-7401 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

June 6, 1997


ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800